Remarks

As a result of this amendment, the claims now in the application are claims 24-36, 48-54, 63-74, and 76-90.

In the outstanding Official Action, the Examiner objected to certain language in claims 34, 53, 68 and 74. Those claims have been amended in a manner that is believed to eliminate the language problem noted by the Examiner.

The Examiner also rejected claims 24-36 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This amendment has changed those claims in a manner that Applicants believe eliminate the areas of indefiniteness. Accordingly withdrawal of this ground of rejection is believed to be in order.

Applicants also respectfully request reconsideration of the Examiner's rejections of the claims under 35 U.S.C.103(a) as follows:

(1) claims 24, 26, 31, 35, 36, 48, 54, 63, 69 and 75 as unpatentable over Rosier (4,807,643) in view of Manoli (US 4,583,549) and Battmer et al. (US 6,428,484);

(2) claims 25, 27 and 28 as being unpatentable over Rosier, as modified by Manoli and Battmer et al., further in view of Applicant's submission of prior art;

(3) claims 29, 32, 49, 50, 64, 66, 70 and 71 as unpatentable over Rosier as modified by Manoli and Battmer et al., further in view of Spitz et al. (US 5,215,100); and

(4) claims 30, 33, 34, 51-53, 65, 67, 68 and 72-74 as unpatentable over Rosier as modified by Manoli and Battmer et al., further in view of Drongelen (US 6,224,549).

The foregoing request for reconsideration of the rejections under 35 USC 103(a) is made in view of the changes that have been made to the claims, further in view of the following remarks relative to Applicants invention and the above-identified prior art.

The essence of Applicants' invention is that, by utilization of mechanical and electronic localization, it obviates the need for precise electrode placement and knowledge of neuroanatomy (app. page 14, lines 3-6.). With respect to mechanical

localization, Applicants' sensor is designed to facilitate placement of an evoked response detector in the general vicinity of a muscle or nerve segment to be measured (app. page 13, 18-22). To this end Applicants' sensor is unique in that it combines a stimulator and a detector in one integral unit that is constructed so that when the sensor is located with its stimulator at a first superficial location over a nerve, its detector is oriented relative to the simulator and also automatically positioned in a second superficial location over and in the general vicinity of a second of the muscle or nerve segment that is to be examined (app. page 13, lines 18-21, page 16, lines 21-23, page 17, lines 1-7). In other words, Applicants' sensor is so constructed as to substantially limit the rage of anatomic sites over which the detector can be placed while at the same time automatically placing the detector substantially adjacent to a muscle innervated by a nerve.

With respect to electronic localization, Applicants' invention is adapted to precisely investigate the electro-physiological properties of the region being investigated and to identify the optimal location at which to measure the response evoked by operation of the stimulator, whereby to obtain accurate and reliable measurements (app. page 13, lines 22-23, page 14, lines 1-3). To this end Applicants' invention comprises use of a detector that constitutes a number of electrodes arranged in fixed spatial relationship to one another, and means for sampling the evoked response from all or a section of a muscle and to determine the electrode or combination of electrodes deemed optimal in terms of signal response for performance of nerve conduction studies, all as explained on pages 26-28 of Applicants' specification. In other words, Applicants' invention is configured to evaluate parameters of the signals sensed by the detector and to select those signals which best identify and assess nerve conduction parameters according to the particular neuromuscular pathology that is being evaluated.

The claim changes made by this amendment are intended to better distinguish Applicants' invention from the prior art relied upon by the Examiner. For convenience and in the interest of brevity, the following discussion is concerned primarily with

previously submitted independent claims 24, 48, 63 and 69 (all of which have been amended so as to better define Applicants' invention), but they apply equally well to the claims that depend from those independent claims.

Thus method claim 24 is hereby amended so as to require that the connector be configured to mechanically orient the stimulator and the detector relative to one another and to automatically position the detector substantially adjacent to a second anatomical site when the stimulator is placed substantially adjacent to a first anatomical site on the surface of an individual. Method claim 24 further requires in steps (c) and (d) that the stimulator provide a stimulus to the first anatomical site and the detector detect response signals produced at the second anatomical site, with those signals being processed to evaluate selective parameters of those signals and to compare those response signals according to the evaluated selected parameters. Claim 24 further calls in step (e) for selection of at least one electrode on the basis of the comparison of step (d) which detects a response signal characteristic of the second anatomical site.

Method claim 48 is similar to claim 24 except that it uses different language to characterize the flexile connector. In this case, it calls for a flexible connector that is "constructed and shaped to effect mechanical localization of the detector relative to the stimulator whereby the detector will be automatically positioned substantially adjacent to the second anatomical site where the stimulator is placed substantially adjacent to the first anatomical site". Additionally claim 48 requires evaluating "two or more selected parameters of the response signals" and comparing the response signals according to the evaluated selected parameters for the purpose of selecting at least one electrode detecting a response signal characteristic of the second anatomical site.

Independent apparatus claims 63 and 69 contain language similar to that of claim 24 in defining the connector and its relationship to the stimulator and detector. Claims 63 and 69 also require that the apparatus be configured to effect selection of at least one electrode detecting a response signal characteristic of a second anatomical site. Claim 63 further requires that the selection of the at least one electrode be

accomplished by an algorithm involving evaluation of several parameters of signals detected by the electrodes, while claim 69 calls for the selection of at least one electrode that detects an optimum response signal. In both independent apparatus claims, the connector connects the stimulator to the detector connecter to form an integral structure.

Applicants submit that the several patents relied upon by the Examiner in support of the several Section 103(a) rejections do not render obvious and unpatentable the method and apparatus defined by claims 24, 48, 63 and 69 and also the other previously submitted claims that depend therefrom.

Rosier admittedly discloses apparatus for conducting nerve conduction studies that uses separate stimulus and detector electrodes. However, Rosier does not show or teach the following: (1) a unitary sensor comprising a stimulator, a detector, and a flexible connector physically connecting the stimulator and detector; (2) a plurality of detector electrodes in fixed spatial relation to one another; (3) a connector that orients the detector relative to the stimulator or that automatically positions the detector on a second anatomical site when the stimulator is positioned on a first anatomical site; and (4) means or a method for comparing the responses of several detector electrodes and determining which of the electrodes is positioned to provide an optimum response.

The Manoli patent discloses an electrode pad for passively monitoring a heart's electrical activity. As such the pad comprises several like recording electrodes, but does not teach a stimulator or any relationship with a stimulator. Manoli's apparatus is similar to Applicants' invention in only two respects: (a) it has several electrodes in fixed spatial relationship with one another; and (2) it comprises multiple layers of material including a base layer, and a layer of conductive traces. However, there is no teaching in Manoli relating to nerve conduction studies. Moreover, Manoli does not have multiple electrodes for the same purpose as Applicants, i.e., to determine which of multiple electrodes are positioned to provide an optimum response signal. Therefore, it would

not be obvious to use a flexible multi-electrode pad as taught by Manoli to modify the apparatus or procedures disclosed or rendered obvious by Rosier.

Battmer et al is of interest in that it discloses an implantable device comprising a plurality of electrodes for measuring or picking up auditory evoked potentials, and means including a multiplexer for selecting two of the electrodes that form an optimum couple for picking up evoked potentials. However, Battmer et al. does not teach or suggest construction or use of a sensor that combines a stimulator and a multi-electrode physically connected together in the manner specified by Applicants' claims. Moreover, Battmer et al. do not teach or suggest Applicants' mode of determining the optimum performance electrodes or the use of same to conduct external nerve conductions studies. Therefore, it would not be obvious to combine Battmer et al. with Rosier and Manoli to provide a method or apparatus as taught and claimed by Applicants.

The Examiner's reliance on Applicants' disclosure on pages 13 and 25 relative to relevant nerve conduction parameters is noted, but that disclosure does not suffice to make up for the deficiencies of Rosier, Manoli and Battmer et al.

The patent to Spitz et al. is relevant in that it discloses a device adapted to conduct carpal tunnel nerve conduction studies and teaches peak to peak amplitude measurements of evoked signals. However, Spitz el al. do not teach or suggest Applicants' scheme for (a) determining which of a plurality of electrodes provide optimal responses for particular nerve conduction studies, and (b) then using the electrode(s) found to provide the optimal response to conduct detailed nerve conductions studies. Consequently Spitz el al. does not make up for the deficiencies of Rosier, Manoli and Battmer et al.

Drongelen is relevant because it teaches frequency spectrum comparison. Otherwise, however, the reference does not make up for the deficiencies of the other references discussed hereinabove.

For the foregoing reasons, Applicants submit that their method and apparatus, as defined by claims 24-36, 48-54, and 63-74, are clearly patentable over the prior art.

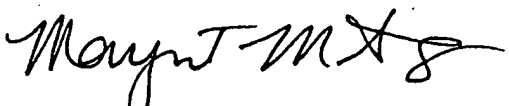
New claims 76-90 are similar to the amended claims and are believed to be patentable for the same reasons. Additionally they add other limitations that distinguish from the prior art relied upon by the Examiner.

This amendment is believed to constitute a full response to the Official Action and to place the application in condition for allowance. Accordingly prompt allowance is respectfully requested.

In the event that any fees may be required in this matter, please charge the same, or credit any overpayment, to Deposit Account No. 16-0221.

Thank you.

Respectfully submitted,



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